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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/543,007

05/02/2006

Franz Freudenthal

PPT001

2439

32047

7590

09/21/2009

GROSSMAN, TUCKER, PERREAULT & PFLEGER, PLLC
55 SOUTH COMMERICAL STREET
MANCHESTER, NH 03101

EXAMINER

OU, JING RUI

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

09/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/543,007	Applicant(s) FREUDENTHAL, FRANZ	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-75 is/are pending in the application.
- 4a) Of the above claim(s) 74 and 75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/12/2006, 05/13/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsive to the preliminary amendment filed on 07/22/2005 and the telephonic Election/Restriction made on 09/10/2009. Claims 40-75 are pending. Claims 40, 67, 71, and 74 are independent. Claims 74 and 75 are withdrawn from consideration.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 40-73, drawn to an apparatus.

Group II, claim(s) 74 and 75, drawn to a method of making an implantable device.

3. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the method can be used to make a stent with a larger length-to-width ratio in a second operating state.

4. During a telephone conversation with Steven Grossman on 09/10/2009 a provisional election was made without traverse to prosecute the invention of Group I, claims 40-73. Affirmation of this election must be made by applicant in replying to this Office action. Claims 74 and 75 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

Art Unit: 3773

subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Drawings

6. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the quality of the drawings is poor. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent

Art Unit: 3773

and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

7. Claim 64 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation "the implantable device is formed from a cut tube, in particular a laser-cut tube, in particular from a tube made of biocompatible material, in particular nitinol or a polycarbonate" does not further limit the recitation in Claim 40.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 40-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 40, the phrase "etc" renders the claim indefinite. See MPEP § 2173.05(d).

Claims 40 and 41 recite "walls" in line 3 of claim 40 and line 4 of claim 41. It is unclear what wall the Applicant refers to in the claims.

Art Unit: 3773

Claim 46 recites the limitation "the application" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 48 recites the limitations "the material concentration" and "the material thickness" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

The language "that partial areas of the support structure are formed from a material of different diameter, or partially different diameters of the material of the support structure are formed by provision of several wires" in Claim 49 is grammatically confusing.

Claim 50 recites the limitation "the amount of material" in line 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 recites the limitation "the two ends" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 52 and 53 recites the limitation "the end" in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claim 55 recites the limitation "the individual parts" in line 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

In Claim 55, it is unclear that how individual parts of the support structure are designed uniformly while corresponding to one another or differing from one another.

Claim 56 recites the limitation "the basic coil shape" in line 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 57 recites the limitation "the ends" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 62 recites the limitation "the edge area" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 63 recites the limitation "retaining wires" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 40-59 and 63-66 rejected under 35 U.S.C. 102(b) as being anticipated by Amplatz et al (US Pat. No.: 5,944,738).

Amplatz et al discloses a device comprising: a support structure (**10**) which has a great length-to-width ratio along an axis in a primary shape (Fig. 5) while having a smaller length-to-width ratio along said axis in a secondary shape (Fig. 7), a proximal portion, and a distal portion (**12 and 14**); the support structure being formed from a single wire-like element by interweaving in a manner of a net (Fig. 5 and Col.5, lines 3-4); wherein the proximal portion/and or distal portion in the secondary shape is substantially flat in a disk shape(Fig. 7); and a delimited inner space (Fig. 5); wherein the proximal portion and the distal portion are placed flat and partially on top of one another (Fig. 2); wherein at least a partial area of the implantable device is folded (Fig.

Art Unit: 3773

5); wherein an eccentrically arranged central through-opening (the central channel space formed in the device) remains in the implantable device in the secondary shape of the support structure (Fig. 7); wherein an intermediate portion (16) having a reduced diameter compared to the proximal portion and distal portion (Fig. 5); wherein the primary shape is asymmetrically or irregularly configured (Fig. 5); wherein the material concentration inside the support structure is different from portion to portion (Fig. 5, the material concentration inside the support structure is different from the proximal end to the central portion); wherein the end of the proximal portion is completely close by provision of a plate element (30); the end of the distal portion or proximal portion has one or more loops which are interlaced in particular with a substantially uniform edge being formed (Fig. 7); wherein the support structure is designed as a two-part unit (12 and 14) connected to one another to form one part; wherein individual parts of the support structure are designed uniformly (Fig. 7); the support structure of the implantable device in the primary shape is configured like a stent (a stent can have any shape); wherein one or more membranes are incorporated into the support structure (Col. 9, lines 55-58); wherein the membrane is formed by inweaving of at least one filament (a mesh is formed by inweaving of at least one filament); and wherein the wire-like element of the implantable device is made of nitinol (Col. 5, lines 48-60).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3773

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of Gainor et al (US Pat. No.: 2002/0169475)

In regard to Claims 60-62, Amplatz et al discloses all the limitations of the claims but fails to disclose that the membrane is made of a material with a cross section differing from that of the wire like element and formed from a wave, scrim. However, Gainor et al teaches device comprising a membrane that is made of a polyester with a cross section differing from that of a wire-like element and formed from a wave, scrim (Fig. 2). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to include a membrane that is made of a polyester with a cross section differing from that of a wire-like element and formed from a wave, scrim to prevent large particles from go through the membrane.

15. Claims 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz et al (US Pat. No.: 5,944,738) in view of Shaw et al (US Pat. No.: 6,171,329).

In regard to Claims 67-73, Amplatz et al discloses all the limitations of the claims but fails to disclose a positioning system.

However, Shaw et al teaches a positioning system, comprising: an advancing element (**62**), a guide wire and/or inner mandrel (**42**), at least one retaining wire (**96**), and an extraction wire (**104**); wherein a retaining wire loop is formed (Fig. 12A). The number of retaining wire and retaining wire loops are merely an obvious designed choice and within one of ordinary skill in the art.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Amplatz et al and Shaw et al before him or her, to modify the system of Amplatz et al to include a positioning system comprising an advancing element, a guide wire and/or inner mandrel, at least one retaining wire, and an extraction wire; wherein a retaining wire loop is formed as taught by Shaw et al.

The suggestion/motivation for doing so would have been to facilitate and enhance the ease of delivering/retracting the implantable device (Shaw et al, Col. 3, lines 23-55)

Therefore, it would have been obvious to combine Shaw et al with Amplatz et al to obtain the invention as specified in the instant claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 20040073242 A1 Chanduszeko, Andrzej J.

US 6911037 B2 Gainor; John et al.

Art Unit: 3773

US 6551344 B2	Thill; Gary A.
US 6468303 B1	Amplatz; Kurt et al.
US 6312446 B1	Huebsch; Joseph et al.
US 6214029 B1	Thill; Gary A. et al.
US 6174322 B1	Schneidt; Bernhard
US 5976174 A	Ruiz; Carlos E.
US 5733294 A	Forber; Simon John et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036.

The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773